

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 355492-2970	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/US2004/007017	International filing date ( <i>day/month/year</i> ) 08 March 2004 (08.03.2004)	Priority date ( <i>day/month/year</i> ) 07 March 2003 (07.03.2003) ]	
International Patent Classification (IPC) or national classification and IPC A61L 31/18, A61P 9/00			
Applicant MICRO THERAPEUTICS, INC.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).
  2. This REPORT consists of a total of 9 sheets, including this cover sheet.
- In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:
 

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input checked="" type="checkbox"/> Box No. II	Priority
<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application
4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 740 14 35	Date of issuance of this report 09 September 2005 (09.09.2005)  Authorized officer  <div style="text-align: center; font-weight: bold;">Simin Baharlou</div> Telephone No. +41 22 338 71 30
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# PATENT COOPERATION TREATY

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From the  
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY  
(PCT Rule 43bis.1)

Date of mailing 16 AUG 2004  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/US2004/007017

International filing date (day/month/year)  
08.03.2004

Priority date (day/month/year)  
07.03.2003

International Patent Classification (IPC) or both national classification and IPC  
A61L31/18, A61P9/00

Applicant  
MICRO THERAPEUTICS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability.
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
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**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

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PCT/US2004/007017

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**Box No. II    Priority**

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1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2004/007017

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 17-21

because:

- ☒ the said international application, or the said claims Nos. 17-21 (industrial applicability) relate to the following subject matter which does not require an international preliminary examination (*specify*):

**see separate sheet**

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
  - the written form ☐ has not been furnished
  - ☐ does not comply with the standard
  - the computer readable form ☐ has not been furnished
  - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

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**Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	
	No: Claims	1-23
Inventive step (IS)	Yes: Claims	
	No: Claims	1-23
Industrial applicability (IA)	Yes: Claims	1-16,22,23
	No: Claims	17-21

**2. Citations and explanations**

**see separate sheet**

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING  
AUTHORITY (SEPARATE SHEET)**

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**Item III**

1. Claims 17-21 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

2. The following documents are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

- D1: US-A-5 667 767<sup>✓</sup> (EVANS SCOTT ET AL) 16 September 1997 (1997-09-16)
- D2: US-A-5 695 480<sup>✓</sup> (EVANS SCOTT ET AL) 9 December 1997 (1997-12-09)
- D3: WO 00/71170 A<sup>✓</sup> (ROTH NOAH M ; GREFF RICHARD J (US); TRAN CHINH N (US); WHALEN THOMAS J) 30 November 2000 (2000-11-30)
- D4: WO 00/56370 A<sup>✓</sup> (DOLMATCH BART ; RICCI CHARLIE (US); CRAGG ANDREW H (US); GREFF RICHARD) 28 September 2000 (2000-09-28)
- D5: US 2002/187102 A1 (EVANS SCOTT ET AL) 12 December 2002 (2002-12-12)
- D6: US-B-6 454 7381<sup>✓</sup> (WHALEN II TOM ET AL) 24 September 2002 (2002-09-24)
- D7: US-A-5 925 683<sup>✓</sup> (PARK SANGSOO) 20 July 1999 (1999-07-20)
- D8: MOTTU F ET AL: "Iodine-containing cellulose mixed esters as radiopaque polymers for direct embolization of cerebral aneurysms and arteriovenous malformations." January 2002 (2002-01), BIOMATERIALS. JAN 2002, VOL. 23, NR. 1, PAGE(S) 121 - 131 , XP002291570 ISSN: 0142-9612
- D9: WRIGHT K C ET AL: "Experimental evaluation of cellulose acetate NF and ethylene-vinyl alcohol copolymer for selective arterial embolization." JOURNAL OF VASCULAR AND INTERVENTIONAL RADIOLOGY : JVIR. OCT 1999, vol. 10, no. 9, October 1999 (1999-10), pages 1207-1218, XP000800903 ISSN: 1051-0443

The documents considered in the present processing are consecutively numbered D1-D9; this numbering results from the citations D1-D9 found in the Search Report (SR) of the corresponding PCT application. It will be adhered to in the rest of the procedure. The cited passage(s) for each citation will be considered

unless otherwise specified.

**Item V**

**Novelty**

3. The technical features of claims 1-23 are disclosed by documents D1-D8 and therefore lack novelty in terms of Art 33 (2) PCT.

D1 discloses embolizing compositions comprising a polymer, solvent and up to about 40 wt% of a contrast agent. The compositions are said to form a coherent solid material and the particle size of the contrast agent is maintained at about 2µm to enhance formation of the suspension.

D2 provides embolic compositions with improved visualization using contrast agent particle sizes of less than 10µm. The contrast agent is present at up to 40 wt%.

D3, D5, D6 also discloses embolizing compositions comprising a polymer, solvent and up to 40 wt% of a contrast agent.

D4 provides example compositions containing 40 wt% contrast agent. The ratio of polymer to contrast agent is 0.0625 and 0.2 for examples E and F respectively.

D7 discloses in example 1, a composition comprising 46%wt of a contrast agent, ultravist 370. The polymer composition obstructed blood flow when injected into the ret mirabile.

D8 appears to provide iodine containing polymer compositions with sufficient radiopacity for use as embolization materials. Iodine was present in amounts of 41.4 and 44.7 wt%.

4. D9 is a general review of known products Embolix C and E containing 30 %wt tantalum and was not considered to anticipate the subject matter of the claims.

**Further Remarks:**

**Industrial Applicability** (Art 33(4) PCT).

5. For the assessment of the present claims 17-21 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a



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AUTHORITY (SEPARATE SHEET)**

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known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.